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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,195	04/01/2004	Johan Frostegard	FROSTEGARD=1B	6441

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/814,195	FROSTEGARD, JOHAN	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/720,967.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's response to the non-final action mailed May 18, 2005 is acknowledged (paper filed 8/2/05). In the amendment filed therein claims 1, 2, 3 and 5-19 have been modified. Currently claims 1-19 are pending and under consideration.

2. Objections and/or objections of record not reiterated below have been withdrawn.

REJECTIONS WITHDRAWN

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-19 are withdrawn from provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-23 of copending Application No. 10/814,194 in view of Ostermann et al. (Thrombosis Research, 52, 529-540, 1988). Both applications are drawn to kits comprising the same reagents (means for determining antibodies to PAF and/or an antigen capable of binding PAF). Although the preambles are directed to different utilities, this is not given patentable weight in the product (kit) claims.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention. See *In re Casey*, 370 F.2d 576, 152 USPQ 235(CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459(CCPA 1963).

Application No. 10/814,194 differs from the instant invention in not specifically teaching a means for determining patients at risk for having cardiovascular and/or early atherosclerosis (correlate PAF concentration to cardiovascular disease and/or early atherosclerosis).

However, Ostermann et al. teach PAF quantification in serum and plasma as well as its correlation/diagnosis (discrimination) in Atherosclerotic patients. See abstract and page 531 2nd paragraph. Thirty-Six health volunteers and 40 atherosclerotic patients were evaluated in the study. Blood samples were analyzed to determine PAF concentration. The results showed a significant increase in serum PAF levels of patients suffering from coronary artery disease. Page 536, last paragraph. The researchers also measured plasma levels. See page 538.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to correlate the measurement of PAF concentrations in serum and plasma patients with cardiovascular disease such as atherosclerosis as taught by Ostermann et al. in the kit of Application No. 10/814,194 because Ostermann et al. taught the critical role of PAF in myocardial infarction/atherosclerosis and its accuracy of correctly classifying subjects. See abstract. Ostermann et al. further taught that PAF could discriminate between low and high-risk groups and was an improvement over other commonly utilized discriminators (total cholesterol, VLDL/LDL-cholesterol, apo). See page 537 2nd paragraph.

One having ordinary skill in the art would have been motivated to do this because the early detection of such disorders is both beneficial in possible prevention and treatment of the disease.

5. This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicants contend that claims 12-23 in co-pending application #10/814,194 have been deleted. Therein obviating the provisional obvious double patenting rejection. This argument was carefully considered and found persuasive. Accordingly the ODP is withdrawn.

REJECTIONS MAINTAINED

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

I. Claims 1-2 and 5-7 are rejected under 35 U.S.C.103(a) as being unpatentable over Barquinero et al. (Lupus, 1994, 3, 55-58) in view of Foster et al. (U.S. Patent#4,444,879).

Barquinero et al. teach an ELISA assay to measure antibodies against platelet-activating factor (PAF) in patients with autoimmune diseases. Specifically blood sample from patients with SLE (systemic lupus crythematosus), PAPS (antiphospholip syndrome), and syphilis. SLE is vascular diseases (relating to blood vessels). SLE includes severe inflammation of blood vessels (see The signet Mosby medical encyclopedia definition attached). See abstract and page 55 Introduction and page 56 "ELISA technique for anti-PAF".

With respect to the means for determining patients at risk for having cardiovascular disease and/or early atherosclerosis, it is noted that Barquinero et al. teach the measurement of PAF in patients with autoimmune disease such as SLE. SLE includes blood vessel inflammation, which could lead to cardiovascular disease (risk).

Since there is no corresponding structure, etc., in the specification to limit the means step or step plus function limitation, an equivalent is any element that performs the specified function.

Although Barquinero et al. teach the reagents required by the claims; they do not specifically teach the reagents in kit configurations. In other words, the reference fails to teach the reagents as a kit. However, kits are well known embodiments for assay reagents. Foster et al. (U.S. Patent #4,444,879) describe one example. In their patent kits including the reactant reagents, a microplate, positive controls, negative controls, standards, and instructions are taught. The reagents are compartmentalized or packaged separately for utility. See figure 6, and column 15, lines 10-34.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the detection assay reagents as taught by Barquinero et al. and format them into a kit because Foster et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay. Kits are also economically beneficial in reagent distribution.

II. Claims 3-4 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barquinero et al. (Lupus, 1994, 3, 55-58) in view of Foster et al. (U.S. Patent#4,444,879) and further in view of Ostermann et al. (Thrombosis Research, 52, 529-540, 1988).

Please see Barquinero et al. in view of Foster et al. as set forth above.

Barquinero et al. in view of Foster et al. differ from the instant invention in not specifically teaching PAF as an indicator for cardiovascular diseases such as atherosclerosis via PAF quantification in serum and plasma.

However, Ostermann et al. teach PAF quantification in serum and plasma as well as its correlation/diagnosis (discrimination) in Atherosclerotic patients. See abstract and page 531 2nd paragraph. Thirty-Six health volunteers and 40 atherosclerotic patients were evaluated in the study. Blood samples were analyzed to determine PAF concentration. The results showed a significant increase in serum PAF levels of patients suffering from coronary artery disease. Page 536, last paragraph. The researchers also measured plasma levels. See page 538.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to measure PAF concentrations in serum and plasma patients with cardiovascular disease such as atherosclerosis as taught by Ostermann et al. in the method of Barquinero et al. because Ostermann et al. teach the critical role of PAF in myocardial infarction/atherosclerosis and its accuracy of correctly classifying subjects. See abstract. Ostermann et al. further teach that PAF could discriminate between low and high-risk groups and was an improvement over other commonly utilized discriminators (total cholesterol, VLDL/LDL-cholesterol, apo). See page 537 2nd paragraph.

One having ordinary skill in the art would have been motivated to do this because the early detection of such disorders is both beneficial in possible prevention and treatment of the disease.

III. Claims 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barquinero et al. (Lupus, 1994, 3, 55-58) in view of Foster et al. (U.S. Patent#4,444,879) and further in view of Karasawa et al.(Lipids, Vol. 26, No. 12, 1991, pages 1122-1125).

Please see Barquinero et al. in view of Foster et al. as set forth above.

Barquinero et al. in view of Foster et al. differ from the instant invention in not specifically teaching the detection of various known naturally occurring phospholipids related to PAF(phospholine). These forms include lyosPAF , PC(phosphatidylcholine), and lysoPC(lysophosphatidylcholine).

However, Karasawa et al. disclose systems to detect antibodies to PAF. The reference further evaluates related phospholipids (PC, lysoPC, lysoPAF, PE, PS, PG, PI, PA, SM, and CL. See abstract. Each phospholipids reacts differently with regard to binding antibodies to PAF. In some instances the related phospholipids cross react with PAF antibodies. See page 1123 Results. This cross-reaction could result in erroneous results in PAF antibody levels.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use various known PAF related phospholipids to evaluate cross reactivity and allow for accurate detection of PAF antibodies as taught by Karasawa et al. in the kit of Barquinero et al. (Lupus, 1994, 3, 55-58) in view of Foster et al. (U.S. Patent#4,444,879) because Karasawa et al. disclosed that these related PAF phospholipids could possible cross-react with PAF. See page 1125.

One having ordinary skill in the art would have been motivated to do this to account for cross-reactivity and provide accurate detection of aPAF (antibodies to PAF).

IV. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barquinero et al. (Lupus, 1994, 3, 55-58) in view of Foster et al. (U.S. Patent#4,444,879) and further in view of Ostermann et al. (Thrombosis Research, 52, 529-540, 1988) as applied to claims 3-4, and 8-10 above, and further in view of Karasawa et al.(Lipids, Vol. 26, No. 12, 1991, pages 1122-1125).

Please see Barquinero et al. in view of Foster et al. and further in view of Karasawa et al. as set forth above.

Barquinero et al. in view of Foster et al. and further in view of Karasawa et al. differ from the instant invention in not specifically teaching the detection of various known naturally occurring phospholipids related to PAF(phospholine). These forms include lyosPAF , PC(phosphatidylcholine), and lysoPC(lysophosphatidylcholine).

However, Karasawa et al. disclose systems to detect antibodies to PAF. The reference further evaluates related phospholipids (PC, lysoPC, lysoPAF, PE, PS, PG, PI, PA, SM, and CL. See abstract. Each phospholipids reacts differently with regard to binding antibodies to PAF. In some instances the related phospholipids cross react with PAF antibodies. See page 1123 Results. This cross-reaction could result in erroneous results in PAF antibody levels.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use various known PAF related phospholipids to evaluate cross reactivity and allow for accurate detection of PAF antibodies as taught by Karasawa et al. in the kit of Barquinero et al. in view of Foster et al. and further in view of Karasawa et al. because Karasawa et al. disclosed that these related PAF phospholipids could possible cross-react with PAF. See page 1125.

One having ordinary skill in the art would have been motivated to do this to account for cross-reactivity and provide accurate detection of aPAF (antibodies to PAF).

Response to Arguments

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that the reference of Barquinero teaches the detection of increased serum (antibodies to PAF) binding to PAF in thrombotic manifestations, but the patients already had thrombotic manifestations when the specific binding was demonstrated. This argument was carefully considered but not found persuasive because the claims read on the determination of any "vascular disease". There is no requirement for the patient to be free from vascular disease prior to testing. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the patient to be free from vascular disease prior to testing are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It is also noted that the claims are drawn to a kit (product), therefore there is no requirement that the prior art must suggest that the claimed product will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. *In re Dillon*, 919 F.2d 688, 696, 16 USPQ.2d 1897, 1904 (Fed. Cir. 1990). An obviousness rejection is proper under Dillon so long as the prior art suggests a reason or provides motivation to make the claimed invention, even where the reason or motivation is different from that discovered by applicant.

Applicant also contends that Barquinero also mentions the detection of aCL in addition to aPAF. This argument was carefully considered but not found persuasive because the claims are directed to a kit comprising (open language) a means for the detection of antibodies to PAF (aPAF). This open language allows for additional reagents and would still read on the instant claims.

Applicant also contends that the objects in Barquinero and the present invention are different. Specifically, Barquinero does not use aPAF in risk assessment for developing vascular disease. This argument was carefully considered but not found persuasive because the fact that applicant uses the kit for a different purpose does not alter the conclusion that its use would be prima facie obvious from the purpose disclosed in the reference. *In re Lintner*, 173 USPQ 560.

Applicant argues that Barquinero analyzes blood samples from patients with systemic lupus erythematosus (SLE) and although SLE is a secondary condition leading to cardiovascular disease, other organs are affected as well. This argument was carefully considered but not found persuasive because it has been held that a recitation with respect to the manner in which a claimed product (apparatus/kit) is intended to be employed does not differentiate the claimed product (apparatus/kit) from the prior art. *Ex parte Masham,* 2 USPQ2d 1647 (1987).

Applicant argues that the kit is novel because the method was completely unknown. This argument was carefully considered but not found persuasive because the method is not being considered in the instant application. It is noted that the allowance of claims has no relevancy in considering patentability of claims in another application. *In re Young,* 36 CCPA 886, 173 F.2d 239, 662 OG 947, 81 USPQ 139(1949).

With respect to Foster applicant argues that the deficiencies of Barquinero were not overcome by the combination. However, the test for obviousness is not whether the features of one reference may be bodily incorporated into the other to produce the claimed subject matter but simply what the combination of references makes obvious to one or ordinary skill in the pertinent art. See *In re Bent*, 52 CCPA 850, 144 USPQ 28 (1964). *In re Nievelt*, 179 USPQ 224 (CCPA 1973). Further, a reference is not limited to its working examples, but must be evaluated for what it teaches those of ordinary skill in the art. *In re Boe,* 355 F.2d 961, 148 USPQ 507 (CCPA 1966). *In re Chapman,* 357 F.2d 418, 148 USPQ 711 (CCPA 1966).

Applicant argues that Ostermann measures PAF and not antibodies of PAF (aPAF). However, Ostermann is cited in combination with Barquinero and Foster. Ostermann was cited to show PAF's involvement in cardiovascular diseases while Barquinero in view of Foster taught the determination of aPAF via the binding interaction of PAF/aPAF. The binding interaction of PAF and aPAF has been demonstrated by the prior art. Further, assays to determine the bound complex with respect to normal and diseases samples have been well established (for example, see Baldo et al. figure 1 on page 1138). The measurement of either the antigen or antibody in the bound complex is also taught by the prior art (for example, see Albertini 1984, page 25 1st paragraph). Absent evidence to the contrary, the determination of PAF or antibodies to PAF is deemed routine adjustment. It has been held that the provision of adjustability, where needed, involves only routine skill in the art. *In re Stevens,* 101 USPQ 284 (CCPA 1954).

With respect to Karasawa, Applicant argues that lyso-PAF and lyso-phosphatidylcholine do not bind aPAF. This argument has been carefully considered but is not found persuasive because lyso-phosphatidylcholine is cited in claim 14 and would therefore meet the claim requirements. The rejections are maintained.

7. For reasons aforementioned, no claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Remarks

9. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Baldo et al. (LIPIDS, Vol26, No.12, 1991, 1136-1139) teach an immunoassay technique to measure PAF

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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